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1. Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

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	Section 1 Data requirements: ***3*** Open points: ***11***			Section 1 Data requirements: ***31*** Open points: ***9*** Data gap: ***1***
	Open point 1.1: RMS to amend the list of end points with respect to classification and labeling. (see reporting table 0(1))	Agreed. RMS to amend the list of end points with respect to classification and labeling.	List of end points updated by adding the missing statement.	PRAPeR 01 Meeting (6.– 8.9.2006): Open point fulfilled.
	Open point 1.2: RMS to amend the list of end points with respect to the list of representative uses. (see reporting table 0(4) and 1(13))	Headings should be changed according to the guidance document.	List of end points has been amended with respect to the list of representative uses.	PRAPeR 01 Meeting (6.– 8.9.2006): Open point fulfilled.
	Open point 1.3: RMS to provide a	Monograph should be amended to clarify to which the codes are related.	**Dec 07**: Listed into the addendum to evaluation paper	PRAPeR 01 Meeting (6.– 8.9.2006):

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	corrigendum or revised Volume 4 to clarify the used codes. (see reporting table 0(5))			Open point remains Written procedure: RMS provided an addendum to Volume 4 to clarify the used codes Open point fulfilled
	Open point 1.4: RMS to amend the list of end points with respect to method for the determination of Bis-CHYMP. (see reporting table 1(1) and 1(10))	List of end points should be updated to include this method.	List of end points has been updated to include this method.	PRAPeR 01 Meeting (6.– 8.9.2006): Open point fulfilled.
	Open point 1.5: RMS to amend the list of end points to indicate that a method for blood and tissues (Annex point 4.2.5) is not required. (see reporting table 1(3))	The submitter agrees.	List of end points has been amended to indicate that a method for blood and tissues is not required, due the low toxicity of the compound. However a method is described for urine and whole blood.	PRAPeR 01 Meeting (6.– 8.9.2006): Open point fulfilled

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	Open point 1.6: RMS to amend the list of end points with respect to the validated matrices in food of plant origin. (see reporting table 1(11))	Agreed. List of end points should be updated.	List of end points has been corrected.	PRAPeR 01 Meeting (6.– 8.9.2006): Open point fulfilled.
1.1	Applicant to provide a shelf-life study as well as data on the relative density. (see reporting table 1(12), 1(20) and 1(21))	"Lindsay, D. A. (2004): Frozen Storage Stability of DE-638 in Rice (Raw Agricultural Commodities: Grain, Straw, Immature Forage) and its Processed Products (Bran, Hulls, Polished Rice), Dow AgroSciences unpublished report number 010100.01. Ref. A26" submitted on June 06	Study considered acceptable. Residues of penoxsulam are stable in rice grain, straw, and immature forage when stored frozen at -20°C for up to 732 days. Residues of penoxsulam show to be stable in rice bran, hulls and polished rice when stored frozen at -20°C for up to 390 days.	PRAPeR 01 Meeting (6.– 8.9.2006): Data requirement for relative density addressed. New open point (see o.p. 1.12) RMS to summarise and evaluate the shelf life study for the representative formulation in an addendum and remove the study for the GF-237 formulation from the references relied on. Written procedure:

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				The study for the GF-237 formulation was removed from the list of references relied on Open point fulfilled
	New open point 1.12: RMS to summarise and evaluate the shelf life study for the representative formulation in an addendum and remove the study for the GF-237 formulation from the references relied on.		**Dec 07:** See point 1.1 Listed into the addenda/corrigenda	PRAPeR 01 Meeting (6.– 8.9.2006): Open point open. Written procedure: The study for the GF-237 formulation was removed from the list of references relied on Open point fulfilled
1.2	Applicant to provide data on the oxidising properties of the formulation based on a theoretical assessment or on the EEC method A21. (see reporting table 1(12), 1(18) and 1(19))	"Nelson R.M (2006): Oxidising properties of GF 657 Ref. MA36 " submitted on June 06 IMPORTANT note by RMS: An insertion made by applicant has been removed as contained confidential information about the composition of formulated product.	The current EU test method A 21 to determine oxidizing properties has not to be performed when structural analysis allows to establish that an exothermal reaction with a combustible material is unlike to occur. An assessment of the structures of individual components of VIPER GF-657 formulation as well as of penoxsulam has been performed: none of the formulants nor penoxsulam contain reactive chemical groups (as, for instance, N-halogen	PRAPeR 01 Meeting (6.– 8.9.2006): Data requirement fulfilled New open point (see o.p 1.13) The evaluation in column 3 of the evaluation table to be transferred to an addendum.

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			compounds, organ-nitro compounds and oxyhalogen compounds) that may give the substances oxidising potential. Therefore, none of the components of GF-657 demonstrate oxidising potential. Since the formulation is a simple blend of these components and exhibits good chemical and physical stability on storage, it is reasonable to conclude that GF-657 does not demonstrate oxidising properties.	Written procedure: Applicant provided a theoretical assessment on the oxidising properties of the formulation in an addendum Open point fulfilled
	New open point 1.13: The evaluation in column 3 of the evaluation table to be transferred to an addendum.		**Dec 07**: Done. Listed into the addenda/corrigenda See the previous point 1.2.	PRAPeR 01 Meeting (6.– 8.9.2006): Open point open. Written procedure: Applicant provided a theoretical assessment on the oxidising properties of the formulation in an addendum Open point fulfilled
	Open point 1.7: RMS to remove confidential data form the box "Impurities in technical as" from the list of end points.	Agreed	The confidential information such as used columns or internal standards has been removed from the table.	PRAPeR 01 Meeting (6.– 8.9.2006): Open point fulfilled.

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	(see reporting table 1(14)			
	Open point 1.8: RMS to report the purity of the starting material in a revised Volume 4 or a corrigendum. (see reporting table 1(28))	Applicant provided actual batch analysis of the large scale production or a justification that specified limits above the maximum value found in the batch analyses is acceptable in respect to the toxicological and ecotoxicological assessment.	**Dec 07:** Acceptable. A table with the purity of the starting material during manufacturing has been considered in the Annex C, confidential information, Volume 4	PRAPeR 01 Meeting (6.– 8.9.2006): Open point open. RMS to provide the information on the purity of the starting material in an addendum to vol 4. Written procedure: Applicant provided the information on the purity of the starting material in an addendum to vol 4. Open point fulfilled
1.3	Applicant to provide actual batch analysis of the large scale production or a justification that specified limits above the maximum value found in the batch analyses is acceptable in	Applicant stated that a large scale batch analysis will be available in 2007 meanwhile a 6 batches analysis is provided. "Six typical batches of penoxsulam (DE-638) Technical Grade of Active	Applicant stated that a large scale batch analysis will be available in 2007. A six batch analysis has been however provided confirming that specified limits above the maximum value found in the batch analyses is acceptable in respect to the toxicological and ecotoxicological	PRAPeR 01 Meeting (6.– 8.9.2006): Data requirement open. Large scale batch data is required. A final specification is still required.

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	respect to the toxicological and ecotoxicological assessment. (see reporting table 1(28))	Ingredient were analyzed for active ingredient level, DE-638 related impurities, residual 3,5-lutidine, water and BIS-CHYMP [4(1H)-pyrimidinone, 2-chloro-5-methoxy-, 2-chloro-5-methoxy-4-pyrimidinylhydrazone]. Active ingredient was determined by the internal standard liquid chromatographic (HPLC) method described in DAS-AM-02-003. DE-638 related impurities and 3,5-lutidine were determined by the internal standard liquid chromatographic method described in DAS-AM-01-051. The external standard HPLC method described in DECO GL-AL-MD-2002-002138 was used to measure BIS-CHYMP. Water levels in the 6 batches were measured using Karl Fischer titration.	assessment. The study is under assessment in an addendum to Annex C, Volume 4 . **December 2007:** Annex C, volume 4 contains ~~a~~ comparative table and results from Batches analisis. From that comparison it could be concluded that the lots used for toxicity testing are considered essentially equivalent to the, manufacturing lots, which show the lack of any impurities of toxicological or ecotoxicological concern. Summary in the Addenda to the evaluation paper	Written procedure: Large scale batch data was provided and evaluated in an addendum to vol.4 A final specification is still required Data requirement still open.
1.3	continued Applicant to provide actual batch analysis of the large scale production or a justification that specified limits above the maximum value found in the batch analyses is acceptable in respect to the toxicological and ecotoxicological assessment.	Active ingredient and impurity identification were determined by electrospray liquid chromatography-mass spectrometry (ESI/LC/MS) in the positive ion (PI) and (NI) modes.”		

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	(see reporting table 1(28))	Large scale ready in June 2007 **September 2007:** the study: "Comb A.L Penoxsulam: Batch analysis (ref. A27)" has been submitted. Six batcht of DE-638 Technical Grade of active ingredient were analysed for the active ingredient level, DE-638 related impurities, residual 3,5-litudine, water and low level of BIS-CHYMP. For the determination of the active ingredient and DE-638 related impurities, approximately 100 mg of DE-638 technical was weighed into 100 ml volumetric flask and 5 ml of o-toluic acid solution (internal standard) was added. The flask was diluted to volume with mobile phase, sonicated to dissolve solids and mixed well. The components were determined by HPLC/UV (see Annex C confidential information for further deils at 1.4.2)		
	Open point 1.9: RMS to provide the specified maximum value of the		**Dec 07:** A table with the purity of the starting material during manufacturing has been added to addenda/corrigenda	PRAPeR 01 Meeting (6.– 8.9.2006):

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	relevant impurity in a revised Volume 4 or corrigendum. (see reporting table 1(29)) continued: Open point 1.9: RMS to provide the specified maximum value of the relevant impurity in a revised Volume 4 or corrigendum. (see reporting table 1(29))			Open point open The revised to Annex C, Volume 4 or corrigendum was not provided. Written procedure: RMS provided the specified maximum value of the relevant impurity in a an addendum to Vol. 4 Open point fulfilled Message to tox and ecotox meeting of experts. The ecotoxicology and toxicology experts should carry out an assessment comparing impurity levels in the pilot plant production batches with the material used in their studies as well as those in the proposed specification. (See bottom of the table) Note for the relevant impurity Bis-CHYMP though the specification proposes a level of 0.5 g/kg in the pilot batches it was not determined (<26

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				mg/kg, method not fully validated)
	Message to tox and ecotox meeting of experts. The ecotoxicology and toxicology experts should carry out an assessment comparing impurity levels in the pilot plant production batches with the material used in their studies as well as those in the proposed specification. (See bottom of the table) Note for the relevant impurity Bis-CHYMP though the specification proposes a level of 0.5 g/kg in the pilot batches it was not determined (<26 mg/kg, method not fully validated)			Answer ecotox: Data gap (see 5.1) Notifier to provide the composition of the batches in order to assess the relevance of the impurities. New open point (see 5.4) RMS to check the comparability of the profiles. Written procedure: The comparability of profiles was assessed by RMS. Based on the low level of impurities of any ecotoxicological concern, test material was considered essentially equivalent to the manufacturing lots. EFSA do agree to the assessment Open point fulfilled. Answer tox:

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				Data gap (2.2) Notifier to provide the composition of the batches in order to assess the relevance of the impurities. New open point (2.7) RMS to check the comparability of the batches used in the tox studies and the proposed specification
	Open point 1.10: RMS to provide CAS numbers of formulants in a revised Volume 4 or corrigendum. (see reporting table 1(31))		**Dec 07:** Annex C, Confidential information amended to include this information.	PRAPeR 01 Meeting (6.– 8.9.2006): Open point open. Information to be provided in a corrigendum. Written procedure: CAS numbers of formulants were included in an addendum to Vol. 4 Open point fulfilled

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	Open point 1.11: RMS to provide validation data (incl. the used UV wavelength) for the analytical method used for the determination of the relevant impurity Bis-CHYMP in a revised Volume 4 or corrigendum. (see reporting table 1(32) and 1(33))		**Dec 07:** Summary of validation data (incl. the used UV wavelength) for the analytical method used for the determination of the relevant impurity Bis-CHYMP,has been considered in a revised addenda/corrigenda	PRAPeR 01 Meeting (6.– 8.9.2006): Open point open. Information to be provided in a corrigendum. Written procedure: Information was provided in an addendum Open point fulfilled
1.3	Data gap identified at PRAPeR 01: Applicant to clarify what happened to batches out of specification with respect to the specified minimum purity.	Batches which were out of specification were re-purified to meet specifications using procedures outlined in the manufacturing description,	Indicated in the up dated version JII (April 08) Document JII, sect. 1.8, pag. 4, (Annex C, Confidential information)	PRAPeR 01 Meeting (6.– 8.9.2006): Data gap open. Written procedure: Information provided. Data gap closed.

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	New open point 1.14 RMS to submit the updated versions of the end points and the evaluation table to the EFSA for distribution.		Submitted as requested by EPCO manual	PRAPeR 01 Meeting (6.– 8.9.2006): Open point open. Written procedure: Open point fulfilled
	New open point 1.15 RMS to amend the list of end points		End point amended	Open point open. Noted changes / clarifications to be made to the end points Written procedure: Open point fulfilled

2 Mammalian toxicology

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	Section 2 Data requirements: ***1*** Open points: ***5***			Section 2 Data requirements: ***1*** Data gaps: ***1*** Open points: ***1***
	Open point 2.1: RMS to provide a revised Vol.1, level 3. AOEL to be confirmed in an experts' meeting. (see reporting table 2(5))	Applicant position paper attached *[Attachment has been removed by EFSA for confidentiality reason.]*	Position paper from notifier received on July 2006. RMS does not understand the question raised by the notifier, since in the monograph and in the list of end-points the proposed AOEL is 0.18 mg/kg bw/d based on a 90 day study on dog. However, if other MSs think that the AOEL needs to be confirmed, then RMS agrees that the matter should be discussed in an experts' meeting.	PRAPeR 04 Meeting (25. - 29.9.2006): Open point open, AOEL confirmed, but revised Vol. 1, level 3 not submitted. PRAPeR 14 (22. – 26.1.2007): Open point fulfilled.
	Open point 2.2: RMS to provide a separate addendum 1 with revised dermal absorption. Dermal absorption to be	Applicant position paper attached *[Attachment has been removed by EFSA for confidentiality reason.]*	Position paper Position paper from notifier received on July 2006. RMS agrees that the matter should be discussed in an experts' meeting. If the results of the meeting will require a review of dermal	PRAPeR 04 Meeting (25. - 29.9.2006): Open point fulfilled.

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	discussed in an experts' meeting. (see reporting table 2(7))		absorption, then an addendum will be prepared.	Dermal absorption 10% default value for concentrate and dilution.
	Open point 2.3: According to the agreed AOEL and dermal absorption, a confirmation/revision of the exposure estimates will be needed. (see reporting table 2(7))	According to the agreed AOEL and dermal absorption, a confirmation/revision of the exposure estimates will be needed. See above	According to the agreed AOEL and dermal absorption in an experts' meeting, a confirmation/revision of the exposure estimates will be needed. See above	PRAPeR 04 Meeting (25. - 29.9.2006): Open point still open. PRAPeR 14 (22. – 26.1.2007): Open point fulfilled.
	Open point 2.4: RMS to provide an addendum with the argumentation related to the ARfD. ARfD to be confirmed in an experts' meeting.		Under the conditions of the acute oral toxicity study in Fischer 344 rats (Bonnette, K. L., 2000), the acute oral median lethal dose (LD_{50}) of penoxsulam was greater than 5000 mg/kg bw in males and females. In addition, there are no effects on relevant endpoints such as developmental toxicity, neurotoxicity, mutagenicity or specific organ toxicity following repeated exposure to warrant	PRAPeR 04 Meeting (25. - 29.9.2006): Open point open for formal reasons (the addendum is still missing). The arguments provided by the RMS that an ARfD is not needed were agreed on by the experts.

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	(see reporting table 2(8))		establishment of an ARfD. In accordance with Directive criteria 93/21/EEC, penoxsulam is not classified on the basis of acute oral toxicity. Therefore, an acute reference dose (ARfD) is considered as not necessary for penoxsulam. If the expert's meeting will result in a different opinion, then an addendum will be prepared.	PRAPeR 14 (22. – 26.1.2007): Open point fulfilled.
2.1	Notifier to provide a position paper on the relevance of large granular lymphocytic leukaemia in Fisher rats treated with penoxsulam. (see reporting table 2(9))	Range of historical control data from the performing laboratory are stated in the dossier. Notifier provided on June 2006 a collection of 7 publication.	**Dec 07:** Position paper on leukaemia was provided, reference publications were provided. An addendum has been prepared which considers it. Historical control incidences for LGL leukemia within the reporting laboratory ranged from 8–20 of 50 control males with a mean of 14 of 50 rats/group.	PRAPeR 04 Meeting (25. - 29.9.2006): Data requirement fulfilled. New open point (see open point 2.6) RMS to prepare an addendum on the relevance of large granular lymphocytic leukaemia in Fisher rats treated with penoxsulam..

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	New open point 2.6: RMS to prepare an addendum on the relevance of large granular lymphocytic leukaemia in Fisher rats treated with penoxsulam..			PRAPeR 04 Meeting (25. - 29.9.2006): Open point open. PRAPeR 14 (22. – 26.1.2007): Open point fulfilled.
	Open point 2.5: Carcinogenicity of penoxsulam to be discussed in an experts' meeting. (see reporting table 2(9)) continued: Open point 2.5: Carcinogenicity of penoxsulam to be discussed in an experts' meeting. (see reporting table 2(9))	Notifier position paper attached *[Attachment has been removed by EFSA for confidentiality reason.]*	In the chronic toxicity/oncogenicity study in Fischer 344 rats with penoxsulam, statistically significant, non-dose related increases in the incidence of large granular lymphocytic (LGL) leukemia were observed in male rats at all dose levels tested when compared to concurrent controls. However, considering: • the high spontaneous incidence of LGL leukemia in Fischer rats, especially males • the increase in LGL leukemia being limited to one sex (male) and one species (rat) • the lack of a dose-response in both incidence and severity	PRAPeR 04 Meeting (25. - 29.9.2006): Open point open. No conclusion on the carcinogenicity. PRAPeR 14 (22. – 26.1.2007): Open point fulfilled..

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the Evaluation Meeting
			• the lack of any other tumors in either rats or mice • the lack of genotoxicity • the lack any increases in LGL leukemia in rats administered with structural analogs of penoxsulam the LGL leukemia found in this study was considered spontaneous in origin and unrelated to exposure to penoxsulamthe increases in LGL leukemia in male rats following exposure to penoxsulam. In line with the scientific literature, the finding of an increase in LGL leukemia in one sex in a non-dose related incidence, even when statistically significantly identified, is not considered toxicologically relevant for human risk assessment. Leukaemia not relevant.	
	Message from phys-chem: The experts discussed the specification proposed based on the pilot scale batch		**Dec. 07**: Done. Please see the answer to the open point 1.3.	PRAPeR 04 Meeting (25. - 29.9.2006): Data gap:

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	analysis and considered that the specification proposed based on this pilot plant production was unreliable. Therefore the ecotoxicology and toxicology experts should carry out an assessment comparing impurity levels in the pilot plant production batches with the material used in their studies as well as those in the proposed specification. Note for the relevant impurity Bis-CHYMP though the specification proposes a level of 0.5 g/kg in the pilot batches it was not determined (<26 mg/kg, method not fully validated).			Notifier to provide the composition of the batches in order to assess the relevance of the impurities. New open point: RMS to check the comparability of the batches used in the tox studies and the proposed specification Written procedure: Open point open for formal reasons

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2.2	Data gap identified at PRAPeR 04: Notifier to provide the composition of the batches in order to assess the relevance of the impurities.	**September 2007:** the study: "Comb A.L Penoxsulam: Batch analysis (ref. A27)" has been submitted.	**Dec 07:** See point 1,3 and addenda to the evaluation paper. The lots used for toxicity testing are considered essentially equivalent to the manufacturing lots.	PRAPeR 04 Meeting (25. - 29.9.2006): Data gap open. PRAPeR 14 (22. – 26.1.2007): Data gap open. Written procedure: Data gap open for formal reasons
	New open point: 2.7: RMS to check the comparability of the batches used in the tox studies and the proposed specification	**September 2007:** the study: "Comb A.L Penoxsulam: Batch analysis (ref. A27)" has been submitted	**Dec 07:** See point 1,3 and addenda to the evaluation paper. The lots used for toxicity testing are considered essentially equivalent to the manufacturing lots.	PRAPeR 04 Meeting (25. - 29.9.2006): Open point open. PRAPeR 14 (22. – 26.1.2007): Open point open.
	Message from residues to		The point was addressed in the toxicological	PRAPeR 04 Meeting (25. -

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	tox: Two metabolites were found at high levels in rotational crops: BST and BSTCA. Can the tox meeting examine their relevance and recommend toxicological end points to be used in risk assessment (end points of the parent compound or and other end point)? For chemical structures of metabolites BST and BSTCA please refer to DAR, p 38, residue section.		addendum which was discussed on 26th Jan 2007, demonstrating that metabolites of penoxsulam which have passed Step 3 (Hazard Assessment) can be tolerated without further testing, being the threshold of concern of estimated or actual concentrations in ground water of 0.75 µg/l not exceeded. Thus, penoxsulam meets the criteria for consideration for Annex I inclusion.	29.9.2006): No conclusion. PRAPeR 14 (22. – 26.1.2007): No conclusion possible on the data available. New data requirement: Notifier to submit toxicological information on the plant metabolite BSTCA (and pending on further residue data, on BST metabolite)

3. Residues

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	Section 3 Data requirements: - Open points: ***7***			Section 3 Data requirements: ***-/ 1*** Open points: ~~***6***~~ ***/ 1***
	Open point 3.1: RMS to include TMDI according to WHO/FAO European diet and worst case national diet in the listing of end-points. (see reporting table 3(1))		**Dec. 07**: TMDI according to WHO/FAO European diet and worst case national diet has been included in the list of end-points.	PRAPeR 05 Meeting (27 – 29 09.2006): Open point still open. Open point still open as no tox reference values yet derived in the tox meeting. Written procedure: Toxicological reference values were agreed in a second round of experts' discussion in January 2007. No change to initial proposal in the DAR. Open point fulfilled.
	Open point 3.2:		**Dec. 07:** an addendum has been	PRAPeR 05 Meeting (27 – 29 09.2006):

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	RMS provide an addendum on consideration of possible impacts of a later application in practice on the qualitative and quantitative findings in the rice metabolism study. (see reporting table 3(2)) continued: Open point 3.2: RMS provide an addendum on consideration of possible impacts of a later application in practice on the qualitative and quantitative findings in the rice metabolism study. (see reporting table 3(2))		prepared. It has been considered that ^{14}C-Penoxsulam was applied in a single application at a rate of approximately 100 g ai/ha or equivalent to 2.5x the maximum use rate on rice (40 g/ha) to both, the paddy water and the rice foliage at the 5 to 6 leaf stage of development, being this application method considered as the worst-case scenario. Due to the relatively small size of the plants at the time of application, penoxsulam was liberally applied to the water as well as to the rice foliage. Since penoxsulam is rapidly photodegraded in aquatic systems, this application timing maximized the potential exposure of the rice plants to parent penoxsulam and the possibility of photoproduct uptake—both through the root system and through the leaf surface. No photoproducts were observed in the plant tissues (extracted) or the surface rinses conducted at 0 days after treatment	Open point still open. Open point remains open as RMS to transfer into an addendum the explanation why different results are not expected if the metabolism study was carried out at different application timings. Written procedure: Addendum of August 2008 submitted. Open point fulfilled.

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			(DAT), 3, 7, 14 and 30 DAT, due to the primary photodegradation route, which involves breaking the sulfonamide bridge. Immature samples were analyzed at 0, 3, 7, 14 and 30 DAT to elucidate the metabolicpathway while mature samples were harvested at 134 DAT. The same residue profile was observed in the immature samples and at harvest. The residue profile consisted primarily of parent penoxsulam, the 5-OH metabolite of penoxsulam and two other minor metabolites. The 5-OH metabolite reached levels of 30% of the TRR at 30 DAT and remained at 30% of the TRR in the mature straw. However, the concentration of 5-OH decreased to less than 0.010 µg/g in mature straw. The other two metabolites reached levels of about 10-20% of the TRR in the mature straw; corresponding to approximately 0.005 µg/g. Due to their low levels in the mature samples, no attempt was made to identify either of these components.	
	continued: Open point 3.2: RMS provide an addendum on consideration of possible impacts of a later application in practice on the qualitative and quantitative findings in			

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	the rice metabolism study. (see reporting table 3(2))		In addition to maximizing the potential uptake of photoproducts, the early application timing also increased the time for the rice plants to metabolize penoxsulam. Less than 10% of the TRR remained parent penoxsulam in the mature straw. The remainder of the TRR was equally divided among the 5-OH metabolite and the two minor metabolites. Neither penoxsulam nor its metabolites were present in the mature straw at levels greater than 0.010 µg/g (penoxsulam equivalents) and no compounds were detected at greater than 0.001 µg/g in the rice grain. Panicle initiation, the latest application timing, is approximately 30 days later than the application timing in the current study (5 to 6 leaf stage). No differences expected in the residue profiles for rice treated with penoxsulam at either an early (5 to 6 leaf stage) or a later growth stage (panicle initiation), since the pathway of penoxsulam rice metabolism is well	

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	continued: Open point 3.2: RMS provide an addendum on consideration of possible impacts of a later application in practice on the qualitative and quantitative findings in the rice metabolism study. (see reporting table 3(2))		established. Total residue levels in rice tissues rapidly decline during the first 30 days after application—parent and metabolite concentrations at 30 DAT were all less than 0.02 µg/g. Application at panicle initiation should not result in a significant increase in residue levels at harvest. This is confirmed by magnitude of residue studies where no detectable residues of penoxsulam following either application scenario in rice grain were found. The conditions chosen for the rice metabolism study, provided the maximum possibility of identifying all potentially significant components of the crop residue. Different application timings would not yield significantly different qualitative or quantitative results.	

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	Open point 3.3: RMS to propose a residue definition for risk assessment in an addendum (see reporting table 3(8))		Plants: penoxsulam Animal: penoxsulam Soil: penoxsulam Surface water: penoxsulam Ground water: penoxsulam Sediment: penoxsulam Air: penoxsulam	PRAPeR 05 Meeting (27 – 29 09.2006): Open point fulfilled. The residue definition for risk assessment in plant products to be set as the parent compound only. For animal products, a residue definition is not deemed necessary in terms of the use evaluated.
	Open point 3.4: RMS to summarize additional storage stability data covering a period of 24 month in an addendum. (see reporting table 3(11))	"Lindsay, D. A. (2004): Frozen Storage Stability of DE-638 in Rice (Raw Agricultural Commodities: Grain, Straw, Immature Forage) and its Processed Products (Bran, Hulls, Polished Rice), Dow AgroSciences unpublished report number 010100.01. Ref. A26" submitted on June 06	**Dec. 07 :** Report received, assessed in the addendum to DAR. Control samples of rice grain, straw, immature forage, and the rice processed products bran, hulls, and polished rice were fortified at 0.10 mg/kg (a concentration tenfold above the validated analytical method limit of quantisation of 0.01 mg/kg) with penoxsulam and stored in polypropylene containers. The fortified samples were stored frozen at –20 ± 5°C. Residues of penoxsulam are stable in rice grain, straw, and immature forage when stored frozen at -20°C for up to	PRAPeR 05 Meeting (27 – 29 09.2006): Open point still open. RMS to present the evaluation of the additional storage stability data of raw and processed rice samples under frozen conditions.in an addendum and amend the list of end-points accordingly. Written procedure: Addendum of August 2008 submitted, but

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			732 days. Residues of penoxsulam are stable in rice bran, hulls and polished rice when stored frozen at -20°C for up to 390 days.	new data not peer reviewed. Open point fulfilled.
	Open point 3.5: RMS to present total radioactive residues (TRR) in rotational crops in an addendum. (see reporting table 3(13))		**Dec 07**: Tables summarized in the addenda/corrigenda to the evaluation paper. *[Attachment has been removed by EFSA.]*	PRAPeR 05 Meeting (27 – 29 09.2006): Open point still open. RMS should summarise all additional information with regard to residues in rotational crops including the table presented in the experts' meeting in an addendum. The addendum should also include data on a planting back interval of 30 days, if available. Written procedure: No data other than for 90 days are available to address residues in rotational crops. Refer to data requirement in open point

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				3.6 Open point closed.
	Open point 3.6: RMS to discuss the role of metabolites BST and BSTCA not found in primary but in rotational crops in an addendum. (see reporting table 3(14))		The structure for BST being corrected in a corrigendum to DAR **Jan. 07**: BST and BSTCA have been evaluated and determined to be of no toxicological concern (see January 2007 Toxicology Addendum, Section 5.7.1). Based on these data, there are no concerns for these metabolites in rotational crops.	PRAPeR 05 Meeting (27 – 29 09.2006): Open point still open. The relevance of metabolites BST and BSTCA has not yet been agreed. Consideration of the relevance of metabolites, residues levels and livestock exposure is needed with regard to a particular crop rotation practice in the rice growing MS when authorisation is sought on MS level. It might be necessary to request additional data to address the issue sufficiently. Written procedure: Open point still open.

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				Data requirement: Applicant to address residues in succeeding crops, in particular in view of levels of non-rat metabolite BSTCA and its potential degradate BST
	Open point 3.7: RMS to perform a new consumer exposure/risk assessment in an addendum by taking into account the most recent GEMS/food diet figures and also consumption figures for young children. (see reporting table 3(17))	A report has been submitted in June 2006 with an assessment performed considering the regional GEMS diet.	**Dec. 07:** New exposure risk assessment performed: higher exposure is for toddler and accounts to 0.1% of ADI. It can be concluded that it is extremely unlikely that, in the requested condition of use, any European could ingest enough residues of penoxsulam to exceed the ADI. Therefore, the risk to consumers can be regarded as low.	PRAPeR 05 Meeting (27 – 29 09.2006): Open point still open. The calculation of the TMDI can not be finalized as no agreed tox reference values are available. Written procedure: Addendum of August 2008 provided. Estimates not peer reviewed. Open point fulfilled.

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	Message from residues to tox: New message for tox meeting: Two metabolites were found at high level in rotational crops: BST and BSTCA. Can the tox meeting examine the relevance and recommend toxicological endpoints to be used in risk assessment (end point of the parent compound or any other end point)?			PRAPeR 05 Meeting (27 – 29 09.2006): Answer from tox: Metabolites BST and BSTCA were not detected in the rat metabolism and therefore no data are available. In this case the notifier is asked to provide information on whether or not BST and BSTCA are of toxicological relevance and to provide the related data.

4. Environmental fate and behaviour

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	Section 4 Data requirements: ***3*** Open points: ***8***			Section 4 Data requirements: ~~***3***~~ ***0*** Data gaps: ***1*** Open points: ~~***3***~~ ***0***
4.1	Applicant to provide argumentation on their selection of Koc values used to calculate a mean value for use in PEC calculations. (see reporting table 4(4))	Provided.	Clarification provided by applicant, and summarized in the list of end point into the revised fate section attached. *[The attached list of end points has been removed by EFSA.]* **Dec. 07:** addenda/corrigenda prepared.	PRAPeR 02 Meeting (11.– 14.9.2006): Data requirement remains formally open. RMS to prepare an addendum on the position paper provided by the applicant. Written procedure: Data requirement fulfilled. The updated list of endpoints that contained the information was included by the RMS in the final addendum.
	Open point 4.1: Endpoints for definition of the residue to be updated to include a list of all major residues that require risk assessments as well a relevant residues for		**Dec. 07:** Endpoints for definition of the residue has been updated to include a list of all major residues that require risk assessments as well relevant residues for monitoring.	PRAPeR 02 Meeting (11.– 14.9.2006): Open point remains open. RMS to update the LoEP as indicated Written procedure:

No.	Column A Conclusions of the EFSA Evaluation Meeting	Column B Comments from the main data submitter / applicant on the EFSA Evaluation Meeting conclusion	Column C Rapporteur Member State comments on main data submitter / applicant comments	Column D Recommendations EPCO Expert Meeting / Conclusions of the evaluation group
	monitoring. (see reporting table 4(9))			Open point fulfilled. The LoEP was not updated by the RMS but has been updated by EFSA.
4.2	Applicant to clarify all assumptions used to calculate metabolite PECgw, to include clear information on how $TWA_{pw,t(close)}$ for both 5-OH and BSTCA were estimated and to present new calculations that use a realistic worst case formation fraction of BSTCA. (see reporting table 4(10))	Provided.	Clarification provided by applicant, and summarized in the list of end point into the revised fate section. See open point 4.1. **Dec. 07:** addenda/corrigenda prepared.	PRAPeR 02 Meeting (11.– 14.9.2006): Data requirement remains formally open. RMS to prepare an addendum on the position paper provided by the applicant. Written procedure: Data requirement fulfilled. The updated list of endpoints that contained the information was included by the RMS in the final addendum.
	Open point 4.2: 'for phenyl and triazolopyrimidine ring radiolabels' still needs to be added to the endpoints to put the mineralization and NER values in context.		Clarification provided by applicant, and summarized in the list of end point into the revised fate section. See open point 4.1.	PRAPeR 02 Meeting (11.– 14.9.2006): Open point fulfilled.

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	(see reporting table 4(14))			
	Open point 4.3: 'for phenyl and triazolopyrimidine ring radiolabels' and 'moist soil first order DT50 19 days at 25°C summer sunlight at 40°N (r^2=0.9)' still need to be added to the endpoints. (see reporting table 4(15))	.	Clarification provided by applicant, and summarized in the list of end point into the revised fate section. See open point 4.1.	PRAPeR 02 Meeting (11.– 14.9.2006): Open point fulfilled.
	Open point 4.4: 'non linear first order Modelmaker compartment modelling' still need to be added to the endpoints in the context of the metabolites. (see reporting table 4(16))		Clarification provided by applicant, and summarized in the list of end point into the revised fate section. See open point 4.1.	PRAPeR 02 Meeting (11.– 14.9.2006): Open point fulfilled.

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	Open point 4.5: The DT50 for the major metabolites (5-OH and BSTCA for aerobic studies and 5-OH for anaerobic studies) still need to be added to the endpoints. (see reporting table 4(17))		Clarification provided by applicant, and summarized in the list of end point into the revised fate section. See open point 4.1.	PRAPeR 02 Meeting (11.– 14.9.2006): Open point fulfilled.
4.3	Applicant to provide an audited corrigendum to the original report to correct the Kf, 1/n and Kfoc values for the Amagon soil. Provision by the end of June 2006 would be appreciated. (see reporting table 4(21))	Amagon soil is non-EU and not used in calculations, provided as supplementary information and in the report ID.990058	**Dec. 07:** Applicant has stated in its comments that the Kf and 1/n values for the Amagon soil reported in the original study were incorrectly calculated. Agreed.	PRAPeR 02 Meeting (11.– 14.9.2006): Data requirement remains formally open. Written procedure: Data gap. A data gap has been included in the EFSA conclusion.
	Open point 4.6: RMS to check that Koc were not used to calculate the metabolite PEC. If they were used the values should be added to the method of		Clarification provided by applicant, and summarized in the list of end point into the revised fate section. See open point 4.1.	PRAPeR 02 Meeting (11.– 14.9.2006): Open point fulfilled.

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	calculation box. (see reporting table 4(25))			
	Open point 4.7: RMS to check that Koc were not used to calculate the metabolite PEC. If they were used the values should be added to the method of calculation box. (see reporting table 4(28)		Clarification provided by applicant, and summarized in the list of end point into the revised fate section. See open point 4.1.	PRAPeR 02 Meeting (11.– 14.9.2006): Open point fulfilled.
	Open point 4.8: After data requirement 4.2 has been addressed the endpoints will need appropriately updating with the necessary information in the method of calculation box. (see reporting table 4(30))		**Dec. 07:** Clarification provided by applicant, and summarized in the list of end point into the revised fate section. See open point 4.1.	PRAPeR 02 Meeting (11.– 14.9.2006): Open point remains open. Written procedure: Open point fulfilled. The LoEP was appropriately updated by the RMS.
	New open point 4.9:		**Dec 07:** list of end points updated.	PRAPeR 02 Meeting (11.– 14.9.2006):

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	RMS to update LoEP as indicated in the discussion table.		Refer also to the addenda.	Open point open Written procedure: Open point fulfilled. The LoEP was not updated by the RMS but has been updated by EFSA.

5. Ecotoxicology

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	Section 5 Data requirements: - Open points: ***3***			Section 5 Data requirements: - Open points: ***4*** Data gaps: ***2***
	Open point 5.1: RMS to present the revised assessment in a revised DAR/corrigendum. (see reporting table 5(3))		**Dec. 07** addenda/corrigenda prepared.	PRAPeR 03 Meeting (11.– 15.9.2006): Open point still open. The list of end points has been amended, but an addendum has not been prepared. Written procedure, RMS is asked to provide an addendum with the calculation to support the long-term TER calculation for mammals based on the rabbit NOAEL value as agreed in the expert meeting
	Open point 5.2: The risk to aquatic plants to be discussed in an experts' meeting.	The study should be considered as a single species study performed with more realistic exposure conditions, as it is aimed to refine the EC50 value of Lemna.	The study should be considered as a single species study with more realistic exposure conditions. It is aimed to refine the EC50 value of Lemna. A single species study with a modified	PRAPeR 03 Meeting (11.– 15.9.2006): Open point open From the available information a risk to

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	(see reporting table 5(7), 5(9), 5(13) and 5(16)) continued: Open point 5.2: The risk to aquatic plants to be discussed in an experts' meeting. (see reporting table 5(7), 5(9), 5(13) and 5(16))	A single species study with a modified exposure regime may be used to refine the risk assessment, provided the initial PEC is used and there is no modification of the trigger TER value of 10 (as stated in Guidange document on Aquatic Toxicology, SANCO/3268/2001 and HARAP). The duration of the test was 14 days longer than the standard test (in accordance to point 5.4.2.1 of the guidance document SANCO/3268/2001) in order to allow a certain environmental fate to take place and also in order to take account of the recovery. Growth rate generate more relevant information on recovery potential than frond count. The refined TERlt exceeds the uncertainty factor of 10, associated with protection of untested species We are not fully agree. Please refer also to comment to Point 9.Tthe	exposure regime may be used to refine the risk assessment, provided the initial PEC is used and there is no modification of the trigger TER value of 10 (SANCO/3268/2001 and HARAP). The duration of the test was 28 days. It is longer than the standard test "to allow a certain environmental fate to take place" (SANCO/3268/2001 Sect. 5.4.2.1) and in order to take account of the recovery. Growth rate generate more relevant information on recovery potential than frond count. The refined TERlt exceeds the uncertainty factor of 10, associated with protection of untested species. Nevertheless, considered the study duration in order to evaluate the recovery potential of Lemna, the use of EC50 as endpoint, instead of the NOEC can be questionable. **Dec 2007:** on October 2007 the notifier submitted a study on the refined	non-target aquatic plants could not be excluded. Therefore further data on recovery potential and variability of sensitivity between aquatic plants could be explored. Data gap see 5.1: Applicant to provide data to demonstrate the recovery potential also for other aquatic plants besides *Lemna* Written procedure The open point was to discuss the risk to aquatic plants in an expert meeting. The issue was discussed and leading to a data gap (see above). Open point closed

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	continued: Open point 5.2: The risk to aquatic plants to be discussed in an experts' meeting.	objective of the higher tier Lemna study was not intended to be a meso/microcosm one; we are of the opinion that it is not necessary to test the whole aquatic plant community as the first step in the refinement of the risk assessment for aquatic plants. is no modification of the TER trigger. Both of these above said provisions were followed in the refined risk assessment, showing any unacceptable risk to aquatic plants and the demonstrating a safe use of the product. Please refer also to comment to Point 9. The frond number is not a population level endpoint with ecological relevance to populations. In fact, this is a similar situation with the algal toxicity bioassays, where it may be considered that effects on individual algal cells are not relevant to population level risk assessment, but rather effects on populations of cells. The persistence of populations in the natural environment depends also upon	exposure assessment for penoxsulam performed at the basin scale level. (ref. K23) **July 08:** Recent studies developed rice-watershed scenarios based on representative rice cultivated basins in Italy and Greece, validated using appropriate monitoring studies. These scenarios were used refining exposure and calculating PECs of penoxsulam in receiving SW systems present in a rice-cultivated watershed in EU. For calculating PECs in receiving SW bodies in the rice-cultivated watersheds was used a combination of two compatible models, RICEWQ and RIVWQ, The fate was predicted using the RICEWQ model. Outputs from the RICEWQ model will include PECs in	

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	(see reporting table 5(7), 5(9), 5(13) and 5(16))	the dynamic parameter of the growth rate of the population which is a factor that counterbalances the death rate of the population. Actually, the individual counts of organisms, fronds or algal cells are static measures of the population size at a particular time and, hence, do not reflect the ongoing growth rate of the population, which is necessary to maintain the species in the environment. Therefore, effects on the growth rate of the population are considered as necessary, as relevant, in the risk assessment of adverse effects of exposure to pesticides on the long term persistence of the species in the environment. Add any other supports if needed	paddy water, paddy soil and groundwater beneath rice paddies. The fate was further assessed using the RIVWQ model. Meteorological datasets derived by the FOCUS scenarios for relevant climatic conditions (eg. Thiva, Piacenza, Seville, Porto) were used for model parameterization. The conclusion is that an adequate risk assessment for penoxsulam in all modelled scenarios was achieved using the 95th percentile PEC_{sw} values derived from higher tier modelling in association with the standard laboratory-derived E_bC_{50} in *Lemna gibba* (14 day E_bC_{50} = 3.29 µg a.s./l) and evaluated against the TER trigger value of 10. A safe use of penoxsulam was demonstrated for aquatic macrophytes. Realistic National scenarios should	

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	continued: Open point 5.2: The risk to aquatic plants to be discussed in an experts' meeting. (see reporting table 5(7), 5(9), 5(13) and 5(16))		furthermore considered at member State level.	
5.1	Data gap identified a PRAPeR 03: Applicant to provide data to demonstrate the recovery potentia also for other aquatic plants besides *Lemna*		**Dec. 07**:See open point 5.2.	PRAPeR 03 Meeting (11.– 15.9.2006): Data gap open. Written procedure Data gap maintained
	Open point 5.3: RMS to clearly indicate in the list of intended uses that the assessment only covers tractor application		**Dec. 07:** Supported intended uses for Annex I listing only covers tractor application technology. Additional application technologies could be examined at Annex III level depending on local uses.	PRAPeR 03 Meeting (11.– 15.9.2006): Open point still open

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	technology. (see reporting table 5(12))			RMS to add information to the list of intended uses. Written procedure A footnote has been added to the GAP table by EFSA, stating that the assessment only covers tractor application technology. Open point close
	Message from the phys-chem meeting: Ecotoxicology and toxicology experts should carry out an assessment comparing impurity levels in the pilot plant production batches with the material used in their studies as well as those in the proposed specification.			Answer: No conclusion can be drawn at this stage and new information is necessary. Data gap (see 5.2) Notifier to provide the composition of the batches in order to assess the relevance of the impurities. New open point (see 5.4) RMS to check the comparability of the

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				profiles.
5.2	Data gap identified at PRAPeR 03: Notifier to provide the composition of the batches in order to assess the relevance of the impurities.	**September 2007:** the study: "Comb A.L Penoxsulam: Batch analysis (ref. A27)" has been submitted	**Dec. 07:** From the results of the 6 batches based on the lack of any impurities of toxicological or ecotoxicological concern, and the evaluation reported in the *addenda*, the lots used for toxicity testing are considered essentially equivalent to the manufacturing lots.Se also open point 1.3.	PRAPeR 03 Meeting (11.– 15.9.2006): Data gap open. Written procedure: RMS provided the specified maximum value of the relevant impurity in a an addendum to Vol. 4 Open point fulfilled
	New open point 5.4 proposed at PRAPeR 03: RMS to check the comparability of the profiles.	**September 2007:** the study: "Comb A.L Penoxsulam: Batch analysis (ref. A27)" has been submitted	**Dec. 07:** From the results of the 6 batches based on the lack of any impurities of toxicological or ecotoxicological concern, and the evaluation reported in the *addenda*, the lots used for toxicity testing are considered essentially equivalent to the manufacturing lots.Se also open point 1.3.	PRAPeR 03 Meeting (11.– 15.9.2006): Open point open Written procedure: The comparability of profiles was assessed by RMS. Based on the low level of impurities of any ecotoxicological concern, test material was considered essentially equivalent to the manufacturing lots. EFSA do agree to the

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				assessment Open point closed.
	New open point proposed by EFSA while drafting the conclusion. Please update the LoE – chapter 6: Effects on non-target species, following the standard format of the EPCO Manual E4.			Written procedure: Open point open

List of representative uses evaluated*

Crop and / or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Rice	Italy	Penoxsulam PENOXSULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broad cast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	200-400	0.0075-0.02	N. N*	
Rice	Spain	Penoxsulam PENOXSULAM	F	Echinochloa crus-galli, sedges and broad leaf	OD	20.4 g/L	Broad cast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	150-400	0.0075-0.027	N. N	

List of representative uses evaluated

Crop and / or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
				weeds.											
Rice	Portugal	Penoxsulam PENOXSULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broad cast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	150-400	0.0075-0.027	N. N	
Rice	Greece	Penoxsulam PENOXSULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broad cast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	300-500	0.006-0.013	N. N	

List of representative uses evaluated

Crop and / or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Rice	France	Penoxsulam PENOXSULAM	F	Echinochloa crus-galli, sedges and broad leaf weeds.	OD	20.4 g/L	Broad cast spray	BBCH 11-31 May-June	1	Not applicable	0.03-0.04	150-300	0.01-0.027	N. N	

Remarks: * Uses for which risk assessment could not been concluded due to lack of essential data are marked grey

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds

(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

(i) g/kg or g/l

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(g) All abbreviations used must be explained
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions